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Date of preparation: October 2022

boostrix

HELP PROTECT YOUR PATIENT AND THEIR BABY

NOW'S THE TIME TO DISCUSS PERTUSSIS MATERNAL VACCINATION[1–4]

boostrix

Tetanus Toxoid, Reduced Diphtheria Toxoid
and Acellular Pertussis Vaccine, Adsorbed

HELP PROTECT YOUR PATIENT AND THEIR BABY

NOW'S THE TIME TO DISCUSS PERTUSSIS MATERNAL VACCINATION[1–4]

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Disease awareness	Recommendations
Mode of action	Safety
Role	Effectiveness
Summary	Immunogenicity

PI SSI

Why it’s important to help protect infants from pertussis through maternal immunization:[5–7]

Pertussis is a **highly contagious** respiratory tract disease, which is **more contagious than flu**[5,8]

66%

of pertussis cases reported in **babies <1 year old** occurred in those aged ≤3 months*[6]

infants <2 months are too young to be vaccinated against pertussis[7]

Sound of whooping cough

Boostrix is indicated for booster vaccination against diphtheria, tetanus and pertussis in individuals aged 4 years and older[4]
*N=1,933. Based on data for 2018 from EU[6]

Pertussis continues to be a public health concern, even in countries with high vaccination coverage[2]

In infants **younger than 1 year***[9]

~5,100,000

estimated pertussis cases**

85,900

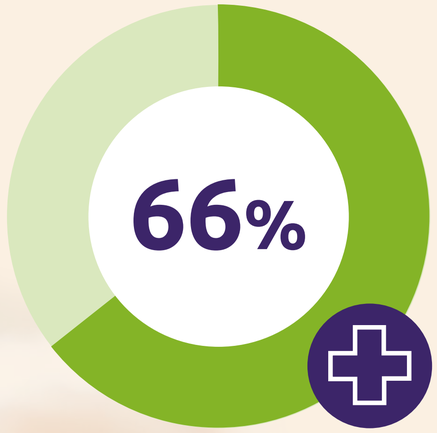
estimated deaths†

*Estimation based on modeling analysis, which showed 24.1 million pertussis cases (3.6% of the population aged <5 years) and 160,700 deaths (0.0% of the population aged <5 years) from pertussis in children younger than 5 years in 2014[9]

**21% of the 24.1 million estimated pertussis cases in children under 5 years of age[9]

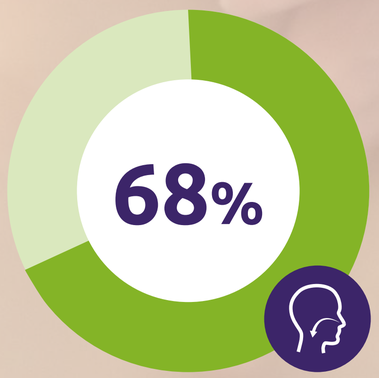
†53% of the 160,700 estimated pertussis-related deaths in children under 5 years of age[9]

Pertussis can cause serious and potentially life-threatening complications in babies[10]

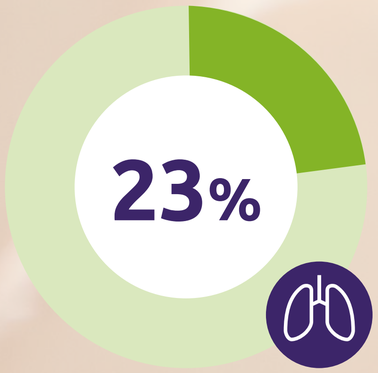


of pertussis cases reported in **babies <1 year** old occurred in those aged **≤3 months***[6]

Approximately half of infants younger than **12 months of age** who get pertussis require hospital treatment, of those infants:[10]



will have **apnea**[10]



develop **pneumonia**[10]

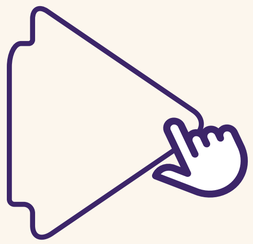
will **die**[10]

*N=1,933. Based on data for 2018 from EU[6]

Newborns and young infants are the most vulnerable to pertussis as they have an “immunity gap”[11]

Primary vaccination calendar with DTaP in Italy[12]

Birth	1 month	2 months	3 months	5 months	11 months	6 years
			DTaP	DTaP	DTaP	DTaP



Drag the arrow to discover the immunity gap

DTaP, acellular diphtheria-tetanus-pertussis

Newborns and young infants are the most vulnerable to pertussis as they have an “immunity gap”[11]

Primary vaccination calendar with DTaP in Italy[12]

Birth	1 month	2 months	3 months	5 months	11 months	6 years
Immunity gap First dose of DTaP is not recommended until 2 months [9,11]			DTaP	DTaP	DTaP	DTaP

DTaP, acellular diphtheria-tetanus-pertussis

Recommendations for use of Tdap vaccination during pregnancy[2,11,13–16]

Recommended by
(local recommending body since [year])[13]

Recommended by
(local gynecology societies)
(placeholder for LOCs)[14]

Tdap, tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed

boostrix

Local Recommendation[13]

[placeholder for LOCs]

Guidelines[14]

[placeholder for LOCs]

How does maternal immunization work?

Passive immunity to the baby[1,2,11]

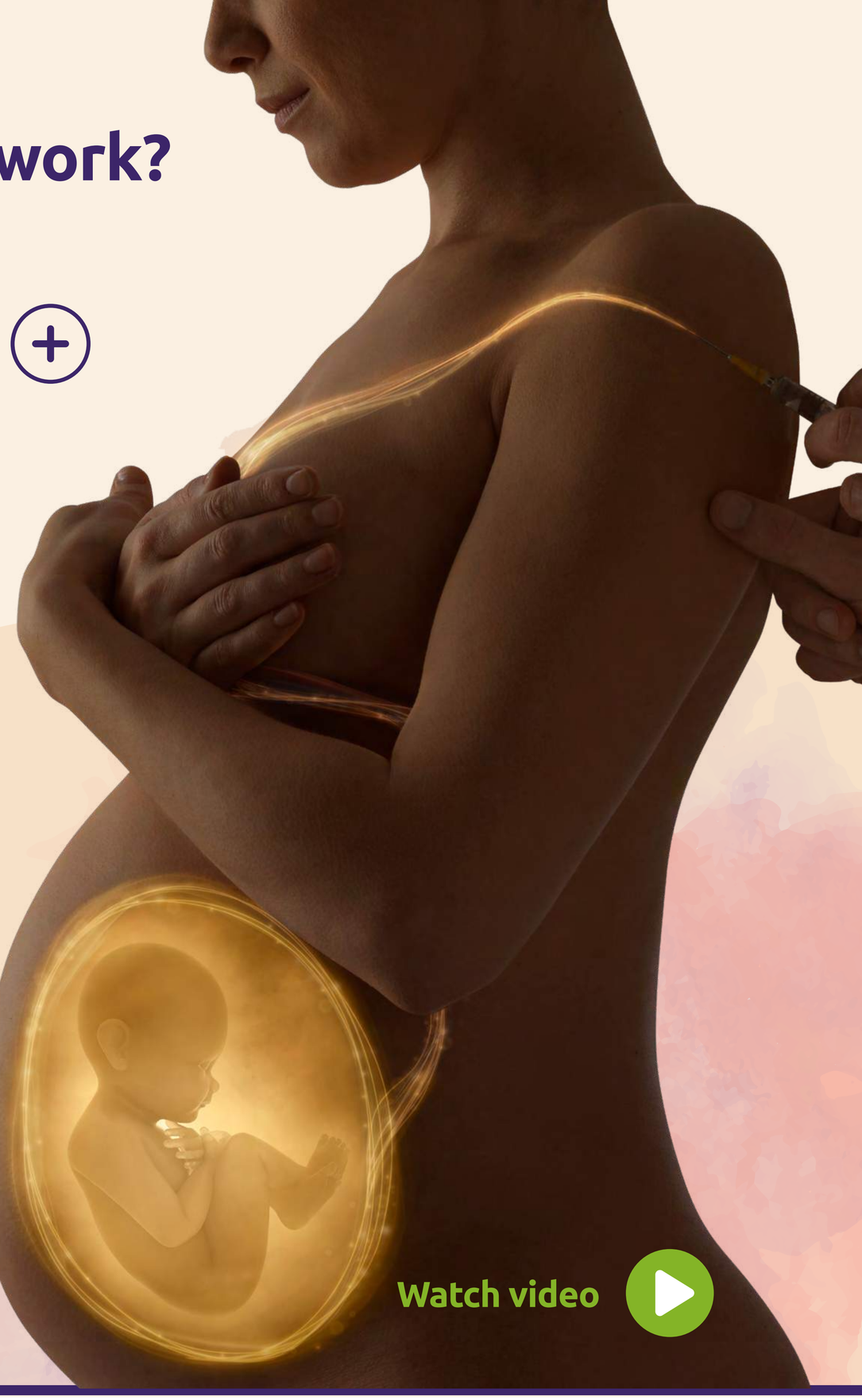
When a pregnant woman receives a **dose of Tdap** vaccine, **her antibodies against pertussis will be passed on to her baby** and may help protect the newborn against pertussis after birth[1,2,11]

1 Tdap dose per pregnancy[4]

To ensure newborns receive the **highest possible protection** against pertussis at birth, it is important that a **Tdap vaccine** is administered **once during each pregnancy**[17]

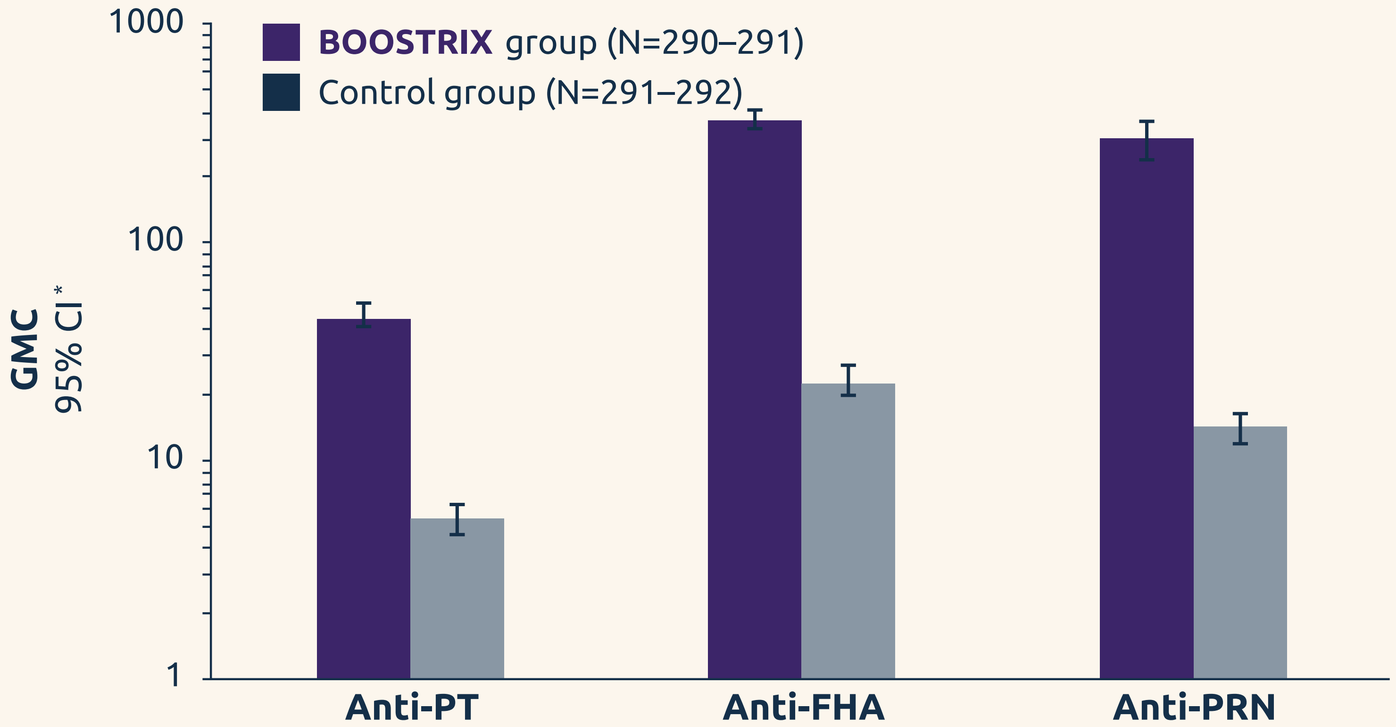
Vaccinate at 27–36 weeks[4,17]

To **maximize the transfer** of maternal antibodies, **vaccination** should be given preferably between **27 and 36 weeks of gestation**[17]



Tdap, tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed

Boostrix immunogenicity



Infants born to women vaccinated with Boostrix in the third trimester had **≥8× higher** antibody GMCs against **PT**, **FHA and PRN** in cord blood compared to the control group**[18]

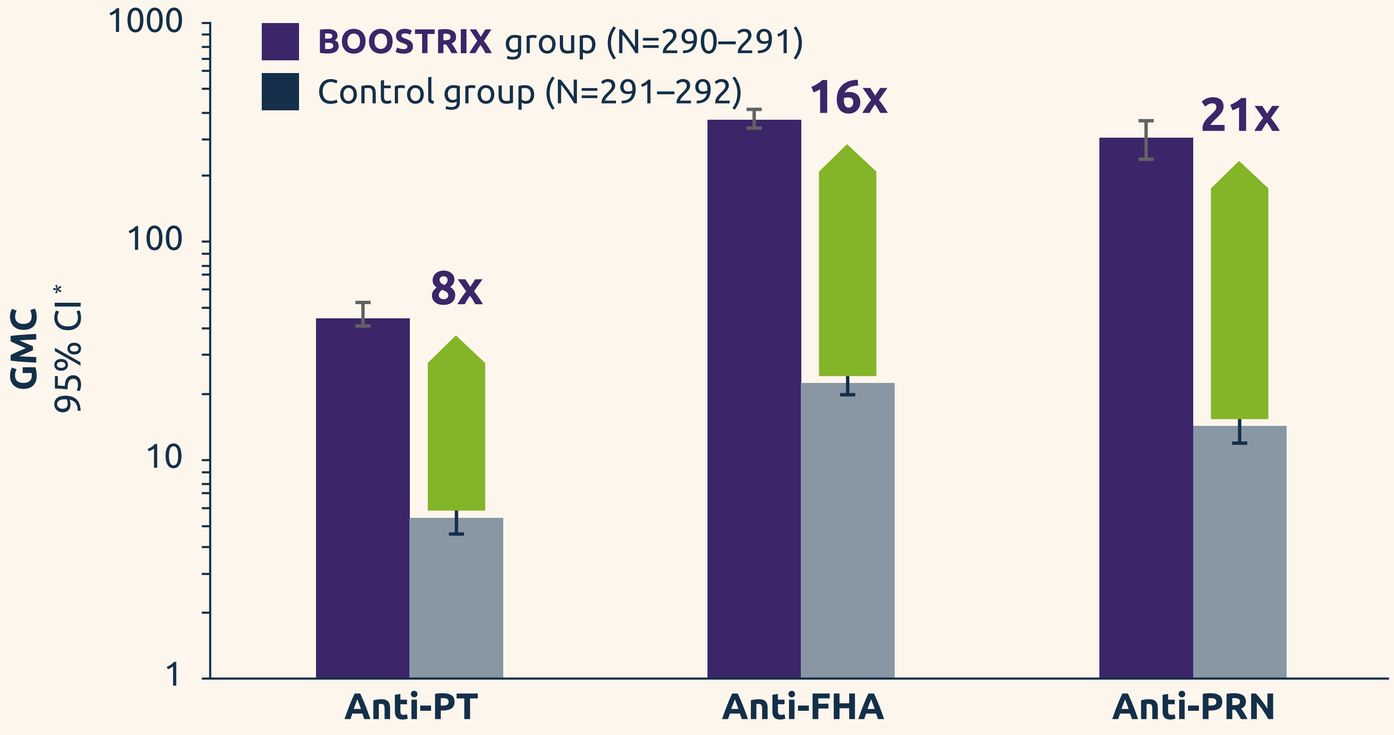
The same results were first published in Perrett *et al.* 2019[18]
The graph has been independently created by GSK from the original data

CI, confidence interval; FHA, filamentous hemagglutinin; GMC, geometric mean concentration; PRN, pertactin; PT, pertussis toxin

For full study design refer to footnotes in this document
*Pre-defined superiority criterion: lower limit of the 95% CI for GMC ratio (Boostrix group/control group) ≥1.5[18]
**Results from a Phase IV, multi-country, randomized, placebo-controlled clinical trial using Boostrix in the third trimester[18]

Study design

Boostrix immunogenicity



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Study design:[18]

Phase IV, observer-blind, randomized, placebo-controlled, multicenter trial

Objective

We performed a randomized, placebo-controlled study in pregnant women of a reduced-antigen-content diphtheria-tetanus-acellular pertussis vaccine (Tdap) vaccine during pregnancy to assess immunogenicity, transfer of maternal pertussis antibodies across the placenta and safety of Tdap vaccination for the mother and neonate. The primary objective was to demonstrate superiority of maternally transferred pertussis antibodies in infant cord blood of Tdap-vaccinated mothers over that of placebo-vaccinated mothers.

Design

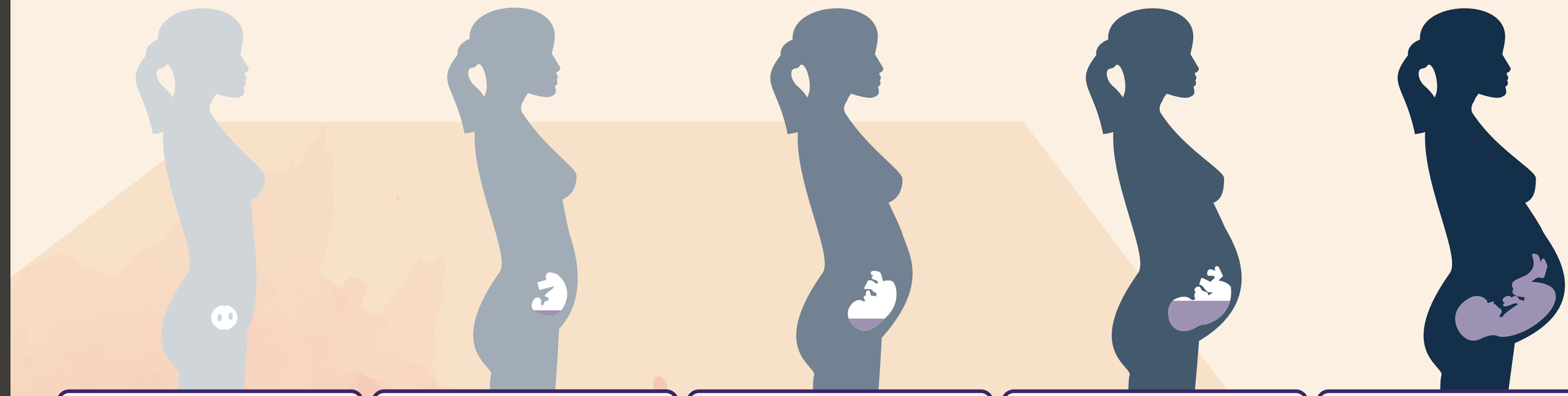
A Phase IV, observer-blind, randomized, placebo-controlled, multicenter trial (NCT02377349).

Method

Healthy pregnant women 18–45 years of age were randomized (1:1) to receive 1 dose of Tdap (Boostrix, GSK) at 27(+0) to 36(+6) weeks gestation and a dose of placebo within 72 hours post delivery (Tdap group) or placebo during pregnancy and Tdap post delivery (control group). Immune responses (geometric mean concentrations [GMC] for pertussis antibodies: anti-FHA, anti-PRN and anti-PT) were assessed before and 1 month after the pregnancy dose; and from the umbilical cord at delivery. Superiority was reached if the lower limit of 95% confidence interval (CI) of the GMC ratios in cord blood was ≥1.5. Solicited adverse events (AE) were recorded for 8 days after each dose, unsolicited for 31 days and pregnancy-/neonate-related AEs of interest throughout the study until 2 months post-delivery.

AE, adverse event; CI, confidence interval; FHA, filamentous hemagglutinin; GMC, geometric mean concentration; PRN, pertactin; PT, pertussis toxin; Tdap, tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed

Placental transfer of disease-specific maternal antibodies is generally linear, with largest transfer in the third trimester[19,20]



First pregnant	Week 13	Weeks 17–22	Weeks 28–32	Full term
None	Starts to increase[19]	5–10% of maternal levels[19]	50% of maternal levels[19]	Exceeds maternal levels by 20–30%[19]

Fetal IgG

Active transport begins after Week 32[20]

Majority of IgG is acquired in the last weeks of pregnancy[19,20]

IgG, immunoglobulin G

Why choose Boostrix for maternal immunization against pertussis[4,20]

Indicated for use during pregnancy[4]

During the **second or third trimester*** for passive protection against pertussis in early infancy[4]

Effectiveness

Up to **91%**** vaccine effectiveness in **preventing pertussis** disease in the **first 3 months of life**[25–27]

Safety

Favorable safety profile when used during pregnancy supported by the largest Phase IV, multi-country, randomized, **placebo-controlled clinical trial** to date[4,18,21–24]

Immunogenicity

Demonstrated **superior levels of maternally transferred pertussis antibodies** in cord blood of vaccinated mothers vs. control group[18]

*The administration of Boostrix should be based on official recommendations[4]

**Boostrix vaccination effectiveness in infants <3 months was 88% (95% CI: 79–93) in the UK (retrospective screening method), 90.9% (95% CI: 56.6–98.1) in Spain (prospective, matched case–control design) and 69% (95% CI: 13–89) in Australia (prospective, matched case–control design)[25–27]

boostrix

Safety data during pregnancy

Studies have shown:

Similar reported rates of
abnormal pregnancy outcomes
or
pregnancy/neonatal-related
adverse events
in **infants born to women vaccinated with Boostrix**
vs. placebo*[18]

Boostrix safety data from the largest Phase IV, multi-country, randomized, placebo-controlled clinical trial to date[18,28,29]

Boostrix prospective safety data from an observational study in New Zealand**[4,30]

Tdap, tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed

*687 pregnant women were vaccinated (n=341, Tdap; n=346, control). Healthy pregnant women 18–45 years of age were randomized (1:1) to receive 1 dose of Tdap (Boostrix, GSK) at 27(+0) to 36(+6) weeks gestation and a dose of placebo. Results from this clinical trial are not included in the label[18]

**Boostrix was administered to pregnant women during the third trimester (793 pregnancy outcomes)[30]

Safety data during pregnancy

Studies have shown:

Similar reported rates of abnormal pregnancy outcomes or pregnancy/neonatal-related adverse events in **infants born to women vaccinated with Boostrix** vs. placebo*[18]

- ✓ **No increased risk** of abnormal pregnancy outcomes or pregnancy/neonatal-related AEs[4,18]
- ✓ Serious AEs were reported in 13.2% of the Tdap group (n=45 in Boostrix group) and in 13.9% of the control group (n=48) and **none were related to Tdap vaccination**[18]
- ✓ Solicited general and unsolicited AEs were **similar between groups**, with local symptoms higher with Tdap vaccination than with placebo[18]

AE, adverse event; Tdap, tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed

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Studies have shown:

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in **infants born to women vaccinated with Boostrix**
vs. placebo*[18]

Boostrix was **well tolerated** in pregnant women, with **no reported serious AEs likely to be caused by the vaccine****[4,30]

Study design

AE, adverse events; Tdap, tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed

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**Boostrix was administered to pregnant women during the third trimester (793 pregnancy outcomes)[30]

Limited data indicate that maternal antibodies may reduce the magnitude of the immune response to some vaccines in infants born to mothers vaccinated with a Tdap vaccine during pregnancy; this phenomenon is known as blunting. The clinical relevance of this observation is unknown.[1]

Study designs

1) Safety of maternal vaccination with Boostrix in the third trimester of pregnancy:[30]

Prospective, observational study conducted in 2 New Zealand regions; 793 women vaccinated in 28–38th week of pregnancy; followed up for 4 weeks post vaccination.

2) Phase IV, observer-blind, randomized, placebo-controlled, multicenter trial:[18]

Objective

We performed a randomized, placebo-controlled study in pregnant women of a reduced-antigen-content diphtheria-tetanus-acellular pertussis vaccine (Tdap) vaccine during pregnancy to assess immunogenicity, transfer of maternal pertussis antibodies across the placenta and safety of Tdap vaccination for the mother and neonate. The primary objective was to demonstrate superiority of maternally transferred pertussis antibodies in infant cord blood of Tdap-vaccinated mothers over that of placebo-vaccinated mothers.

Design

A Phase IV, observer-blind, randomized, placebo-controlled, multicenter trial (NCT02377349).

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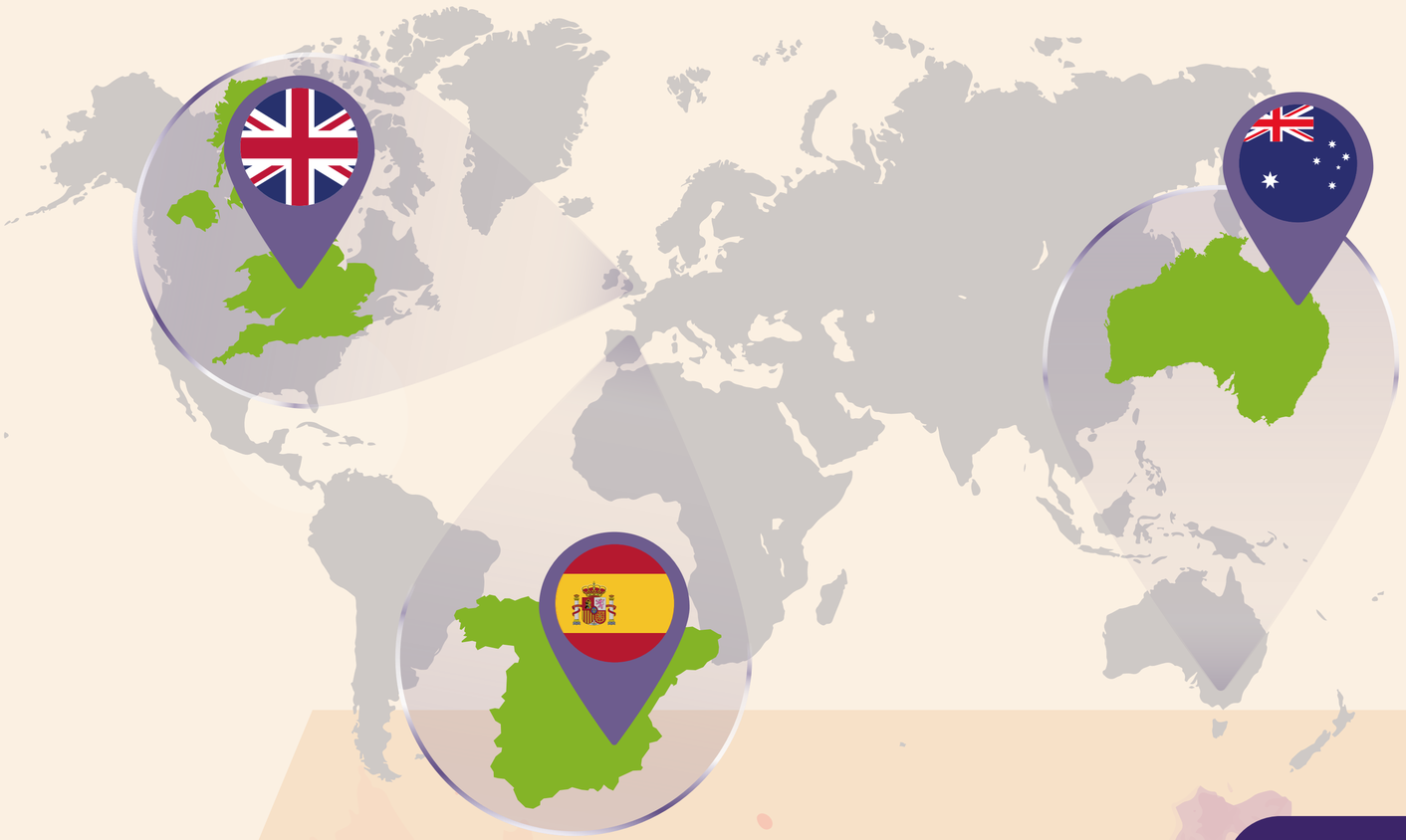
Effectiveness

Demonstrated up to 91% vaccine effectiveness in preventing pertussis disease in the first 3 months of life[25–27]



Study design

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Cl, confidence interval; IPV, inactivated polio virus
For full study design refer to footnotes in this document
If maternal vaccination occurs within two weeks before delivery, vaccine effectiveness in the infant may be lower than the figures in the figure above[4,23]

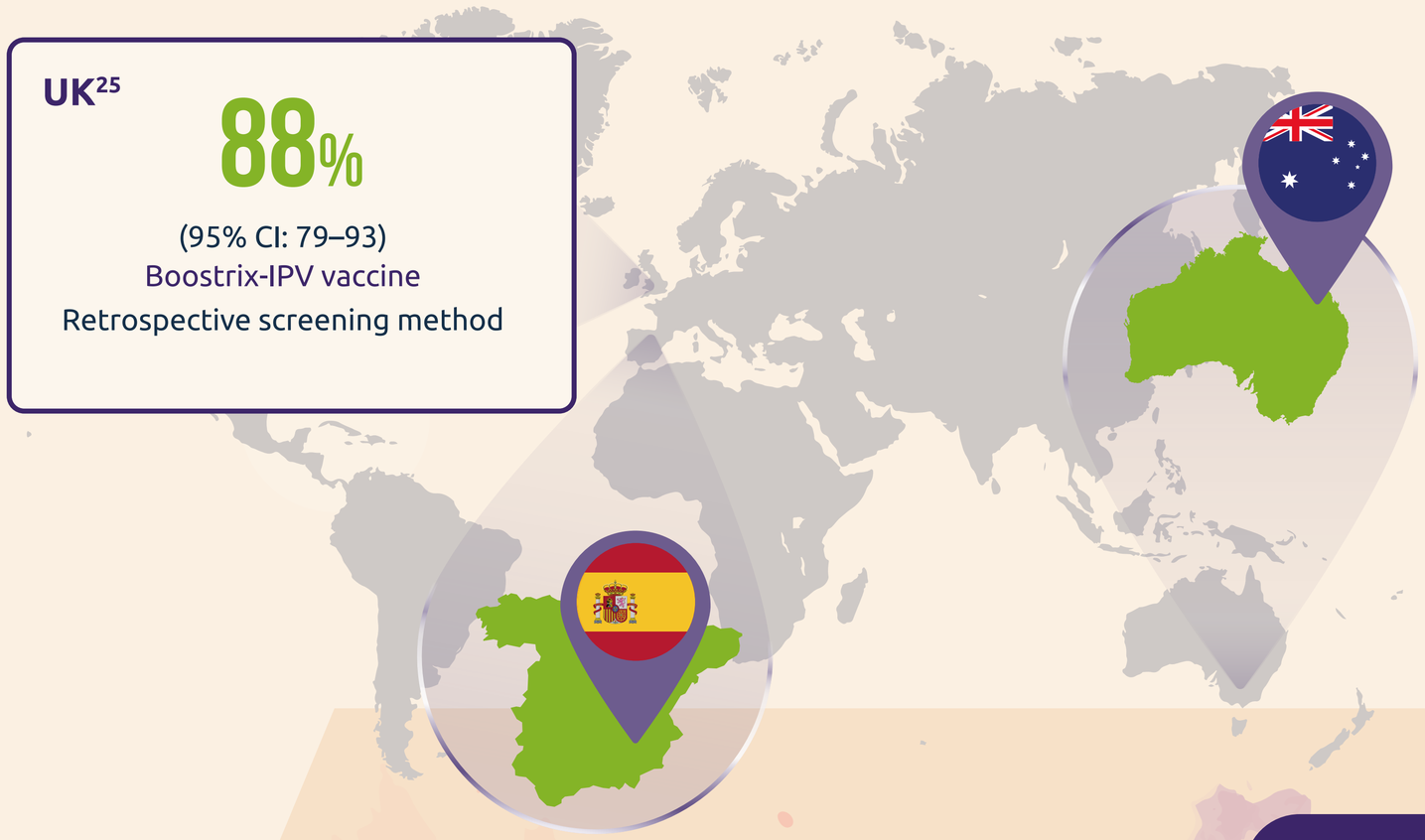
Effectiveness

Demonstrated up to 91% vaccine effectiveness in preventing pertussis disease in the first 3 months of life[25–27]

UK[25]

88%

(95% CI: 79–93)
Boostrix-IPV vaccine
Retrospective screening method



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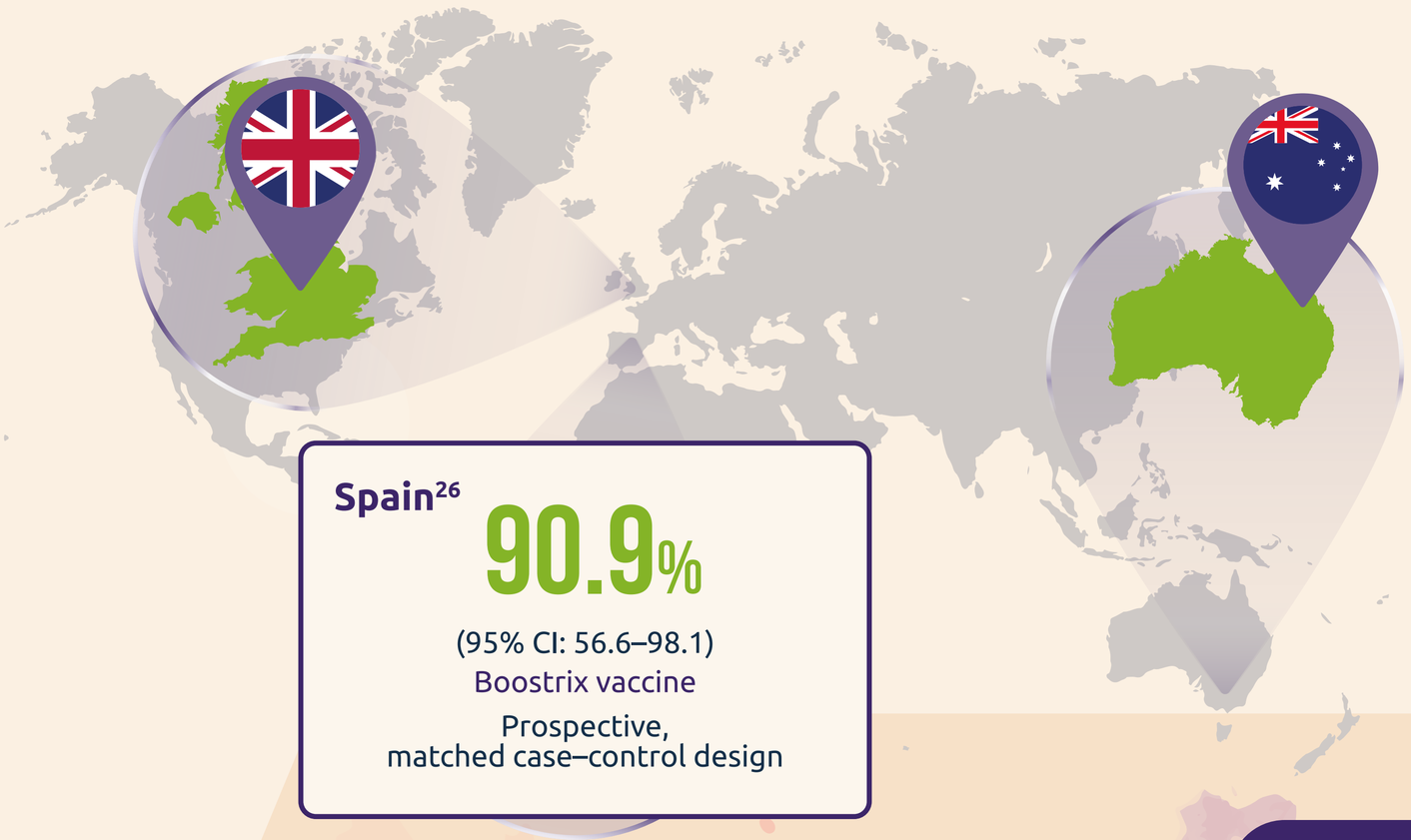

Spain[26]

90.9%

(95% CI: 56.6–98.1)

Boostrix vaccine

Prospective, matched case–control design

Study design

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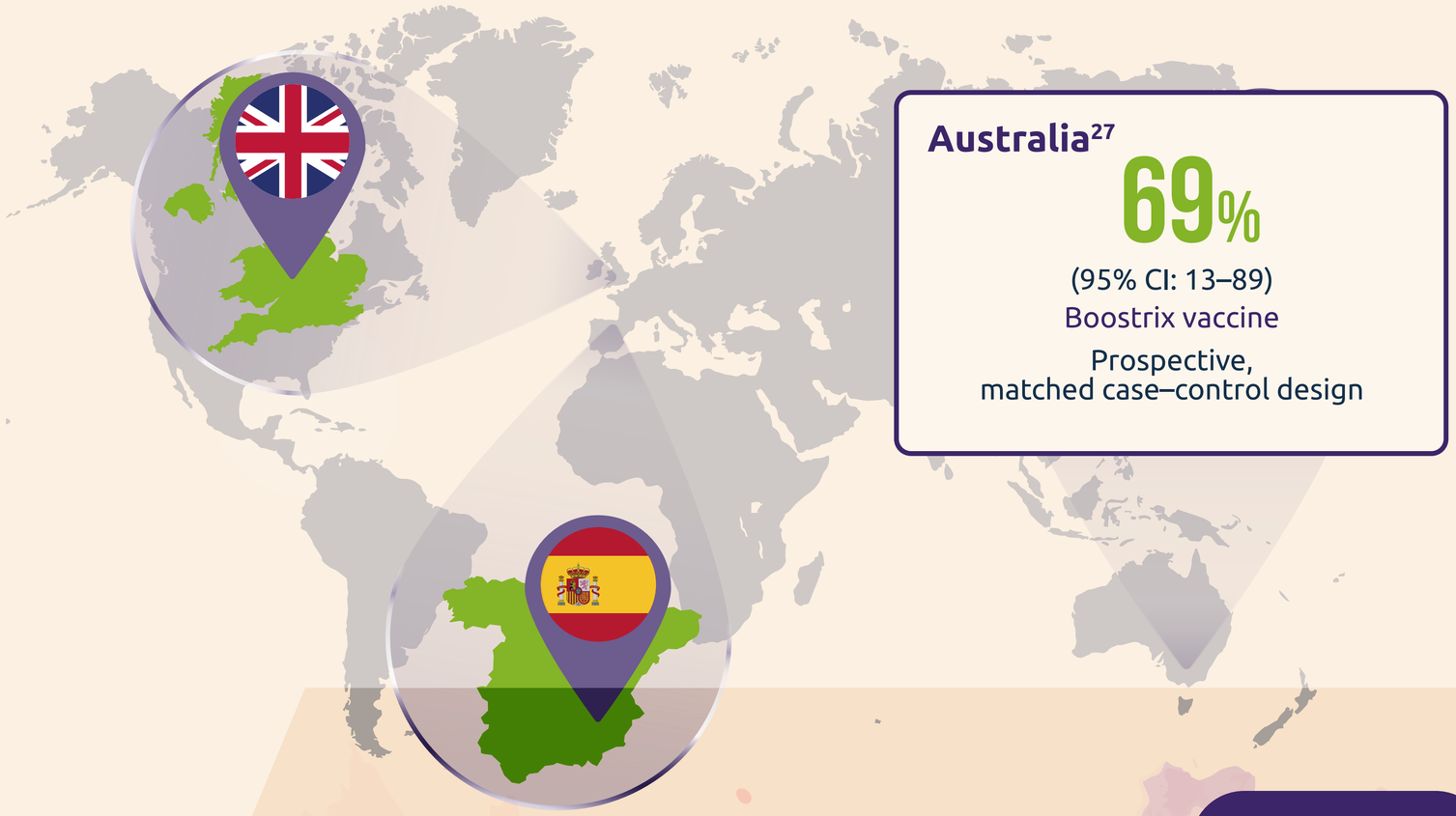

Australia[27]

69%

(95% CI: 13–89)

Boostrix vaccine

Prospective, matched case–control design

Study design

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Study Design

Effectiveness of Boostrix / Boostrix-IPV against pertussis disease in infants <3 months born to women vaccinated in third trimester

UK: Retrospective, database screening method design. A total of 72,781 live births from 1 October 2012 until 31 August 2015 were obtained. Results: A total of 243 cases were obtained giving an overall effectiveness of 91% (95% CI, 88%–94%) for infants <3 months of age. 15 out of a total of 71 pertussis cases were born to mothers vaccinated with Boostrix-IPV giving a VE of 88% (average vaccination coverage was 69.3%).[25]

Spain: Prospective, matched (3:1) case–control study design. Cases were defined as unvaccinated infants less than 3 months-old with pertussis microbiological confirmation by PCR. For every case three unvaccinated controls were selected. Results: 5 of the 22 cases and 41 of the 66 controls were born to vaccinated mothers.[26]

Australia: Prospective, matched (1:1) case–control study design. Cases were defined as infants aged <6 months at symptom onset, with laboratory definitive evidence of pertussis and controls were born in a public hospital in the same local health district where the case was resident. The primary endpoint of this study was VE against pertussis disease in infants <6 months of age; VE in <3 months of age was a sub-analysis (48 matched pairs). Results: 52 of 117 cases <6 months of age and 72 of 117 controls <6 months of age were born to vaccinated mothers. VE was non-significantly protective in this group. 19 of the 48 cases <3 months of age and 33 of the 48 controls <3 months of age were born to vaccinated mothers. VE was significantly protective in this group.[27]

CI, confidence interval; PCR, polymerase chain reaction; VE, vaccine effectiveness

Your role is key in helping to protect newborns from pertussis[31]

Discuss

Discuss the **benefits of vaccination** with pregnant women **early and often**[32]

Recommend

Recommend the Tdap vaccine to pregnant women; recommendations from healthcare providers are **one of the strongest motivators** for pregnant women to get vaccinated[32]

Vaccinate/refer

Offer the Tdap vaccine to pregnant women **or provide referrals** to other vaccination providers[32]

Watch video

Tdap, tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed

Consider maternal vaccination with Boostrix

A complete and reassuring label for pertussis maternal immunization[4,23,24]

Pertussis is more dangerous in infants[6]

Infants under 3 months of age are at higher risk of pertussis-related hospitalizations and deaths[6]

Maternal pertussis vaccination is recommended[13]

(Local Recommendation placeholder)[13]

Why choose boostrix for maternal vaccination?

- ✓ Indicated for use during **pregnancy**[4]
- ✓ Well-established **safety profile**[4,18,30]
- ✓ Effective in the **prevention of pertussis disease** in infants <3 months of age[25–27]

GlaxoSmithKline Biologicals SA. Rixensart, Belgium

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Prescribing Information and Adverse Events

[placeholder for LOCs]

Succinct Safety Information

[placeholder for LOCs]

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